Initial Approval: July 26, 2017

CRITERIA FOR PRIOR AUTHORIZATION

Long-Acting Hemophilia Factors

PROVIDER GROUP Pharmacy

Professional

MANUAL GUIDELINES The following drug requires prior authorization:

Adynovate (antihemophilic factor VIII recombinant, pegylated) Alprolix (coagulation factor IX recombinant, Fc fusion protein) Eloctate (antihemophilic factor VIII recombinant, Fc fusion protein)

Idelvion (coagulation factor IX recombinant, albumin fusion protein (rIX-FP)

Rebinyn (coagulation factor IX recombinant, glycol-pegylated)

CRITERIA FOR ADYNOVATE (must meet all of the following):

- Patient must have a diagnosis of hemophilia A (congenital factor VIII deficiency)
- Must meet one of the following:
 - Routine prophylaxis to reduce the frequency of bleeding episodes (must meet all of the following):
 - Frequency of dosing must not be more frequent than twice weekly
 - Dose must not exceed 50 IU/kg for patients 12 years of age and older, or 70 IU/kg for children less than 12 years of age
 - Exceptions will be made when the provider submits documentation of pharmacokinetic assay testing to indicate that the patient requires more frequent or higher dosing
 - On-demand treatment and control of bleeding episodes (must meet all of the following):
 - Documentation of dose and frequency
 - Rationale for dosing based on patient utilization and/or pharmacokinetic assay testing
 - Perioperative management (must meet all of the following):
 - Documentation of severity of surgery (minor or major)
 - Documentation of dose and frequency
 - Rationale for dosing based on patient utilization and/or pharmacokinetic assay testing

CRITERIA FOR ALPROLIX (must meet all of the following):

- Patient must have a diagnosis of hemophilia B
- Must meet one of the following:
 - Routine prophylaxis to reduce the frequency of bleeding episodes (must meet all of the following):
 - Dose must not exceed 50 IU/kg once weekly or 100 IU/kg once every 10 days
 - Exceptions will be made when the provider submits documentation of pharmacokinetic assay testing to indicate that the patient requires more frequent or higher dosing
 - On-demand treatment and control of bleeding episodes (must meet all of the following):
 - Documentation of severity of bleeding episode (minor/moderate or severe)
 - Documentation of dose and frequency
 - Rationale for dosing based on patient utilization and/or pharmacokinetic assay testing
 - Perioperative management (must meet all of the following):
 - Documentation of severity of surgery (minor/moderate or major)
 - Documentation of dose and frequency
 - Rationale for dosing based on patient utilization and/or pharmacokinetic assay testing

PA Criteria

CRITERIA FOR ELOCTATE (must meet all of the following):

- Patient must have a diagnosis of hemophilia A (congenital factor VIII deficiency)
- Must meet one of the following:
 - o Routine prophylaxis to reduce the frequency of bleeding episodes (must meet all of the following):
 - Frequency of dosing must not be more frequent than every 3 days
 - Dose must not exceed 65 IU/kg for patients 6 years of age and older, or 80 IU/kg for children less than 6 years of age
 - Exceptions will be made when the provider submits documentation of pharmacokinetic assay testing to indicate that the patient requires more frequent or higher dosing
 - On-demand treatment and control of bleeding episodes (must meet all of the following):
 - Documentation of severity of bleeding episode (minor/moderate or severe)
 - Documentation of dose and frequency
 - Rationale for dosing based on patient utilization and/or pharmacokinetic assay testing
 - Perioperative management (must meet all of the following):
 - Documentation of severity of surgery (minor or major)
 - Documentation of dose and frequency
 - Rationale for dosing based on patient utilization and/or pharmacokinetic assay testing

CRITERIA FOR IDELVION (must meet all of the following):

- Patient must have a diagnosis of hemophilia B
- Must meet one of the following:
 - o Routine prophylaxis to reduce the frequency of bleeding episodes (must meet all of the following):
 - Dose must not exceed either 40 IU/kg once every 7 days or 75 IU/kg once every 14 days for patients 12 years of age and older OR 55 IU/kg once every 7 days for children less than 12 years of age
 - Exceptions will be made when the provider submits documentation of pharmacokinetic assay testing to indicate that the patient requires more frequent or higher dosing
 - On-demand treatment and control of bleeding episodes (must meet all of the following):
 - Documentation of severity of bleeding episode (minor/moderate or severe)
 - Documentation of dose and frequency
 - Rationale for dosing based on patient utilization and/or pharmacokinetic assay testing
 - Perioperative management (must meet all of the following):
 - Documentation of severity of surgery (minor/moderate or major)
 - Documentation of dose and frequency
 - Rationale for dosing based on patient utilization and/or pharmacokinetic assay testing

CRITERIA FOR REBINYN (must meet all of the following):

- Patient must have a diagnosis of hemophilia B
- Must meet one of the following:
 - On-demand treatment and control of bleeding episodes (must meet all of the following):
 - Documentation of severity of bleeding episode (minor/moderate or severe)
 - Documentation of dose and frequency
 - Rationale for dosing based on patient utilization and/or pharmacokinetic assay testing
 - o Perioperative management (must meet all of the following):
 - Documentation of severity of surgery (minor/moderate or major)
 - Documentation of dose and frequency
 - Rationale for dosing based on patient utilization and/or pharmacokinetic assay testing

LENGTH OF APPROVAL: 12 months for prophylaxis

3 months for treatment

1 month for perioperative

DRUG UTILIZATION REVIEW COMMITTEE CHAIR	PHARMACY PROGRAM MANAGER
	DIVISION OF HEALTH CARE FINANCE
	KANSAS DEPARTMENT OF HEALTH AND ENVIRONMENT
 Date	

PA Criteria